

**UNITED STATES DISTRICT COURT**  
**FOR THE DISTRICT OF NEW JERSEY**

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**SANDOZ, INC., RAREGEN, LLC,**      **CIVIL ACTION NUMBER:**  
**Plaintiffs,**      **3:19-cv-10170-BRM-LHG**  
**v.**      **PRELIMINARY INJUNCTION**  
**HEARING**  
**UNITED THERAPEUTICS**  
**CORPORATION, SMITHS MEDICAL**  
**ASD, INC.,**  
**Defendants.**

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Martin Luther King Building & U.S. Courthouse  
50 Walnut Street, Newark, New Jersey 07101  
Tuesday, December 10, 2019  
Commencing at 10:50 a.m.

**B E F O R E:**      **THE HONORABLE BRIAN R. MARTINOTTI,**  
                                 **UNITED STATES DISTRICT JUDGE**

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Proceedings recorded by mechanical stenography; transcript  
produced by computer-aided transcription.

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1 (PROCEEDINGS held in open court before The Honorable  
2 BRIAN R. MARTINOTTI, United States District Judge, on December  
3 10, 2019, at 10:50 a.m.)

4 THE COURT: Welcome everyone. Good morning. First,  
5 thank you for accommodating the venue change. Much  
6 appreciated.

7 Before we get started, would conversation help?

8 MR. GLASS: Yes, Your Honor.

9 THE COURT: Can you pick two a side to come in  
10 chambers?

11 MR. KENT: Your Honor, would you like outside  
12 counsel?

13 THE COURT: Two lawyers on each side. Can we do  
14 that?

15 MR. BENNETT: Of course, Your Honor.

16 (A short recess occurred.)

17 THE COURT: Good morning again, counsel.

18 We did have a quick conversation in chambers. It does  
19 not appear at this point we are going to be able to make any  
20 progress. That being said, I did put a text order on the  
21 docket indicating you have a half hour each for your arguments  
22 with 15 minutes. You can use your time putting your  
23 appearances on the record or we can just go. Anyway, go  
24 ahead. Appearances for the record, please. I was teasing.  
25 You could all be seated.

1 MR. GLASS: Thank you, Your Honor. On behalf of  
2 RareGen, my name is Ethan Glass. With me at counsel table is  
3 Thomas Pease and Mike Bonanno. Also, Peter Calamari is here  
4 on behalf of RareGen with the clients.

5 THE COURT: Thank you.

6 MR. KENT: Good morning, Your Honor. Matthew Kent  
7 from Alston & Bird on behalf of plaintiff Sandoz, Inc. And  
8 I'm joined today by Ms. Kramer, Ms. Thompson, and Mr. Parente  
9 also of Alston & Bird. And I have two client representatives  
10 also present.

11 MR. ORLOFSKY: Good morning, Your Honor. Stephen  
12 Orlofsky, Blank Rome, LLP, on behalf of United Therapeutics  
13 Corporation. With me today, Your Honor, are my colleagues  
14 from Williams & Connolly, Jonathan Pitt, Edward Bennett, Sean  
15 Douglass, and Christopher Berg. Also of Blank Rome, Adrienne  
16 Rogove and Michael Darbee.

17 THE COURT: Thank you.

18 MR. BOYLE: Your Honor, Peter Boyle for Smiths  
19 Medical ASD. With me today are my partners Fred Whitmer and  
20 Christina Fahmy. We also have here in the courtroom Gretchen  
21 Randall who is general counsel of Smiths Medical and Meghan  
22 Hansen who is associate general counsel.

23 THE COURT: Okay.

24 Counsel.

25 MR. GLASS: Your Honor, may I take my cell phone to

1 keep track of time?

2 THE COURT: Sure.

3 MR. GLASS: Your Honor, may I also approach? We have  
4 copies of our slides.

5 THE COURT: Okay.

6 MR. GLASS: Your Honor, again, Ethan Glass on behalf  
7 of plaintiff RareGen.

8 Your Honor, we're not going to present the slides on  
9 the screen. We are not as technologically capable as the  
10 other parties.

11 THE COURT: Okay.

12 MR. GLASS: But we have provided copies of the slides  
13 to the defendants.

14 Your Honor, we have also talked with the defendants  
15 about confidentiality, and we have come to an agreement that  
16 the slides that we're showing today and the evidence presented  
17 may be presented in open court, and it may be provided to  
18 everybody's client with the exception being any numbers  
19 relating to price.

20 THE COURT: Okay.

21 MR. GLASS: So we're not going to orally state the  
22 numbers, but I will point you -- if I have a number I want to  
23 show you -- in the slides.

24 THE COURT: Okay.

25 MR. GLASS: Thank you, Your Honor.

1 THE COURT: That's agreed by both sides?

2 MR. BENNETT: Yes, Your Honor. With the addition of  
3 talking about patient population size.

4 THE COURT: Okay.

5 MR. GLASS: Your Honor, as we stated in our brief,  
6 and as the defendants have failed to contest --

7 THE COURT: Where is the irreparable harm to your  
8 clients as we stand here today?

9 MR. GLASS: Thank you, Your Honor.

10 Your Honor, there has been irreparable harm to date,  
11 but there would also be irreparable harm going forward. So  
12 the irreparable harm going forward, which would be remedied by  
13 a preliminary injunction, is the harm to our client's  
14 goodwill. It's the harm --

15 THE COURT: How?

16 MR. GLASS: Because the way that generic supply works  
17 is that the purchasers were -- for this drug is only two  
18 pharmacies, CVS and Accredo. The purchasers are desperately  
19 focused on supply guarantee. So the number one consideration  
20 when you're selling a generic is that you can --

21 THE COURT: You can supply all the drugs that they  
22 need. The problem is delivering it to a patient --

23 MR. GLASS: Correct, Your Honor.

24 THE COURT: -- which is out of your control. It's  
25 not like your factory can't produce the drug.

1 MR. GLASS: That's correct, Your Honor.

2 THE COURT: Okay. How does that transcend into your  
3 reputation?

4 MR. GLASS: So our reputation is hurt because we have  
5 gone on to market with the drug that we can make.

6 THE COURT: Right.

7 MR. GLASS: We approached both specialty pharmacies  
8 in late 2018 to have supply contracts. In those discussions,  
9 the specialty pharmacies told us that all we needed was the  
10 drugs. They had pumps. They had cartridges. We told them we  
11 were going to be able to solve the drug issue for them. They  
12 told us they had pumps and cartridges available.

13 THE COURT: Right.

14 MR. GLASS: Then --

15 THE COURT: Through no fault of you or your client,  
16 there's no cartridges and pumps.

17 MR. GLASS: That's right. And so the problem now is  
18 that these specialty pharmacies, whether it's our fault or  
19 not --

20 THE COURT: Right.

21 MR. GLASS: -- are skeptical that we're going to be  
22 able to deliver on our promises to make the drug available.

23 THE COURT: Well, how can you say that when part of  
24 your papers talk about the fact that the defendants really put  
25 pressure on these pharmacies to exclude you from the market?

1 And then they're going to turn around and say you can't  
2 produce for us when they were complicit in this, perhaps?

3 MR. GLASS: Yes, Your Honor. Because they'll make  
4 the same arguments to the specialty pharmacies that they've  
5 made to Your Honor, which is that we should have anticipated  
6 the anticompetitive conduct. We should have had pumps and  
7 cartridges arranged before we launched, and because we didn't  
8 it's our fault. And then it's just a debate with the  
9 specialty pharmacies. On one hand, we've got the defendants  
10 telling the specialty pharmacies it's our fault. On the other  
11 hand, we're telling the specialty pharmacies it's their fault.  
12 All the while the defendants are supplying both pumps and  
13 cartridges.

14 THE COURT: But the specialty pharmacy says to you we  
15 just need your product. We have a method of delivery. And  
16 then they say to you we don't have a method of delivery  
17 anymore because of what they did. You should have thought  
18 about this the same way they did, to arrange this arrangement  
19 or to get into this arrangement, and that's your fault, even  
20 though we, the pharmacy, said we had a method of delivery?

21 MR. GLASS: So there's two other parties involved in  
22 this.

23 THE COURT: Okay.

24 MR. GLASS: I don't want them to get lost.

25 THE COURT: Okay.



1 MR. GLASS: We've got prescribers and we've got  
2 patients.

3 THE COURT: Right.

4 MR. GLASS: That's in addition to the specialty  
5 pharmacies. So even if we are able to persuade the specialty  
6 pharmacies that it's their fault, while they're telling us  
7 it's our -- they're telling the specialty pharmacies it's our  
8 fault. We need prescribers to prescribe the generic. We need  
9 payers to put on their formularies the generic, and we need  
10 patients to not push back on the prescribers about the  
11 generic. And those are all parties that have no idea that  
12 there was this scheme.

13 THE COURT: Are they part of this lawsuit?

14 MR. GLASS: No, they're not part of this lawsuit.

15 THE COURT: So I come back to how's this harming you,  
16 aside from the fact that your company isn't able to sell the  
17 product and receive money for your product?

18 MR. GLASS: Because -- let me give you an example.  
19 If we receive the injunction today and we had access to  
20 cartridges, that would solve our cartridge problem. But we  
21 would need to go to the prescribers and explain to them what  
22 has happened over the past nine months since they thought we  
23 were going to be able to launch but couldn't.

24 THE COURT: Does a prescriber actually write a  
25 prescription for a generic, or does a prescriber write the

1 prescription and then you go to the pharmacy and the pharmacy  
2 says we have the generic, or you get into an intermediary that  
3 says, you know, the generic is X, the branded is X to the  
4 second power?

5 MR. GLASS: This is why the payers, the insurance  
6 companies are important because it starts with them. The  
7 payers have a formulary which are the drugs that are covered  
8 by their insurance policies. The payers will require  
9 mandatory substitution for certain drugs meaning that when you  
10 or I go to the pharmacy to fill our prescription, the pharmacy  
11 will have to substitute to the generic, regardless of how the  
12 prescription is written.

13 THE COURT: Okay.

14 MR. GLASS: The doctors can check a little box called  
15 "dispense as written" to override that. And so what we need  
16 is we need everybody in this ecosystem to understand that we  
17 have secure supply. We need the insurers to put us on their  
18 formulary, which they have not because we are unable to launch  
19 in subcutaneous. We need the insurers to say that there's  
20 mandatory substitution, which they will only do if there's  
21 insured supply. We need the doctors to not check "dispensed  
22 as written," and we need the specialty pharmacies to actually  
23 stock and dispense.

24 The problem with the theory that the specialty  
25 pharmacies know what's going on is that they're only one piece

1 of the entire puzzle, and that's irreparable injury because  
2 but for the unlawful restraints, we would have launched and  
3 everybody in the ecosystem would have been able to test our  
4 product, see whether or not it should be on formularies, see  
5 whether or not doctors want to prescribe it or mark it  
6 "dispense as written." But now, nine months later, there's  
7 been a significant diminution of our good will. And we can  
8 regularly interact with the prescribers. We have day-to-day  
9 meetings with the prescribers so that they don't check  
10 "dispense as written." We meet with the insurers so they put  
11 us on their formulary. And so that's been a significant  
12 irreparable injury. That continues on. And what we know is  
13 that at some point there's a tipping point. At some point the  
14 prescribers and the insurers and the specialty pharmacies and  
15 the patients give up on the generic supplier. And so our  
16 concern is that that tipping point is in the near future  
17 where even if we got access to cartridges, they will have  
18 written us off. And we have a good example of that. Another  
19 PAH drug, which uses a different approach called Flolan --

20 THE COURT: That was a manufacturing issue, wasn't  
21 it?

22 MR. GLASS: It was, but the problem is --

23 THE COURT: It was their manufacturing plant.

24 MR. GLASS: But the patients and the prescribers --

25 THE COURT: But it was their own fault. I mean, this

1 is -- there's a third party -- I'm saying it, but I don't mean  
2 it -- to blame here.

3 MR. GLASS: There is but nobody knows that. This has  
4 all been confidential. The reason we asked for discovery from  
5 Your Honor is because we approached the specialty pharmacies  
6 and they told us no problem. We started talking with them  
7 about contracts. Then all of a sudden they told us, actually,  
8 we can't stock you. That's the only interaction that alerted  
9 us to this conduct. Everything has been secret. There's been  
10 nothing that's been publicly announced. Nothing made public  
11 through this litigation. There's a protective order, and so  
12 if we go and we tell the insurers and the payers and the  
13 patients actually it was their fault, they're going to say, we  
14 don't know that. There's no evidence of that.

15 And that's the core problem with our irreparable injury  
16 is that every day that goes by, they win. Because not only do  
17 they get the millions of dollars of overpayments by patients,  
18 but they also reduce incrementally the prospect that we will  
19 succeed.

20 THE COURT: So let me ask you the question, which  
21 really is looming. How come, when they knew what was going to  
22 happen in 2015, and they reacted, how come your client didn't  
23 react the same way or act as quick?

24 MR. GLASS: So Mr. Kent will speak specifically to  
25 the Sandoz issues. But I'll tell you, Your Honor, that we

1 didn't know that they were going to corner the market on  
2 cartridges. In fact, from my client's perspective, RareGen's  
3 perspective, we were talking to the specialty pharmacies in  
4 late 2018, and there was no such restriction. What defendants  
5 like to cite is an end-of-life notice for the pump. This  
6 isn't a pump case. We're not here to talk about the pumps.  
7 We understood that the pumps that were in Accredo's possession  
8 were owned by Accredo and available to use with whoever  
9 Accredo dispensed it with.

10 So the idea that 2015 and 2016 we had any notice is  
11 fiction. The first we learned of it, the first we learned of  
12 it, the first we learned of it was when Accredo and CVS  
13 changed abruptly in late 2018, and said, we can no longer talk  
14 with you about stocking your drug. That's when we said, oh,  
15 my gosh, something has changed in the market. We approached  
16 UT and Smiths to try to resolve this, and then we sued in  
17 April. So there was no delay and there was diligence.

18 We also, Your Honor, right when we heard that there was  
19 an issue, started working on alternatives. So we were  
20 reaching out to alternative pump suppliers. We were reaching  
21 out to alternative cartridge suppliers. We wouldn't be here  
22 today if we had an alternative pump or cartridge to offer the  
23 market.

24 THE COURT: And you're still pursuing that avenue?

25 MR. GLASS: We're still pursuing that, Your Honor, to

1 this day. We have a third party who we're working with that  
2 we expect will be able to make cartridges for us eventually,  
3 but we don't have any cartridges today and there's no imminent  
4 cartridge launch.

5 Your Honor, one more thing on irreparable injury, if I  
6 may, and then I'll be happy to answer any more questions Your  
7 Honor has.

8 We had a 180-day exclusivity period. The 180  
9 exclusivity period is statutorily granted to the first ANDA  
10 filer. I'm sure Your Honor has had Hatch-Waxan cases and  
11 knows that when the party who challenges the patent prevails  
12 in court, that party gets 180-day exclusivity. We got that on  
13 a -- based on a settlement.

14 THE COURT: Right.

15 MR. GLASS: Your Honor --

16 THE COURT: So you're saying they entered that  
17 settlement with unclean hands because they knew,  
18 notwithstanding what the agreement was when you were going to  
19 go to launch, you couldn't launch because there was no way to  
20 deliver your product?

21 MR. GLASS: So from my third-party perspective  
22 because RareGen was not a party to that, yes. I'll let Sandoz  
23 specifically discuss what Sandoz expected. But when I look at  
24 that contract and the contract says you may launch on this  
25 date, but they knew that when we got close to launching that

1 they were going to incumber our launch by making the  
2 cartridges unavailable, that is not good faith, Your Honor.

3 And Your Honor, that just goes back to there isn't a  
4 lack of diligence. Sandoz could reasonably expect that if  
5 there was a contractual provision that said that it could  
6 launch, that there wouldn't be any impediments placed by the  
7 parties to that settlement agreement.

8 And Your Honor, the 180-day exclusivity period has  
9 expired. It started and it has expired. That's irreparable  
10 injury because the way generics also work is that the 180  
11 exclusivity grantee, the party that has the right to be the  
12 exclusive generic, almost always has an advantage over the  
13 other generics. Because like the brand, being able to get in  
14 with the doctors, get in with the insurance companies, get in  
15 with the specialty pharmacies and get in with the patients,  
16 there's a reluctance to switch. And that is gone. We will  
17 never get that back.

18 So that's an irreparable injury that continues for us,  
19 in addition to the incrementally diminishing possibility that  
20 we can even succeed.

21 THE COURT: I took you off track. I probably got to  
22 some of what you wanted to talk about.

23 MR. GLASS: For sure, Your Honor.

24 THE COURT: Okay.

25 MR. GLASS: So, Your Honor, just to conclude about

1 the non-likelihood of success factors. So RareGen and Sandoz  
2 are suffering monetary damages. That we don't dispute. But  
3 we also have this irreparable injury component that has  
4 happened and continues.

5 On the other hand, if the injunction is granted, there  
6 is no irreparable injury to the defendants. So when we're  
7 talking about an injunction, we're looking at the but-for  
8 world. The but-for world is Your Honor grants the injunction,  
9 they just have to compete. They have to provide better  
10 quality products and lower prices to keep us from gaining  
11 their customers. That can't be irreparable injury. That  
12 can't be injury at all. That's a benefit.

13 THE COURT: Well, what is the status of these pumps  
14 and cartridges right now? Who owns them?

15 MR. GLASS: So, Your Honor, it depends on which pumps  
16 you're talking about.

17 THE COURT: Right.

18 MR. GLASS: So for pumps, our understanding is  
19 Accredo, the largest specialty pharmacy, which has a  
20 significant portion of the patients that it cares for, has  
21 enough pumps to service all of its patients. Those pumps are  
22 unencumbered by defendants. So those are the pumps that we  
23 would use with Accredo's permission to the patients who are  
24 using the generic treprostinil.

25 THE COURT: Absent the agreement.



1 MR. GLASS: Absent the agreement.

2 THE COURT: Okay.

3 MR. GLASS: There are also pumps that are under  
4 defendant's control, which we're not talking about in our  
5 case. We're not talking about here.

6 THE COURT: They own or they control.

7 MR. GLASS: That they control them and they can use  
8 them, and we're not asking for the injunction to apply to  
9 those pumps.

10 THE COURT: Okay.

11 MR. GLASS: Cartridges, the way that cartridges  
12 worked before the restraints was that a specialty pharmacy  
13 would place an order to Smiths to purchase cartridges. That  
14 order would then be filled, no questions. Just you need 2,000  
15 cartridges, we're going to fill them.

16 Now, the way that the cartridge supply works, is that  
17 specialty pharmacies places an order with UTC, and UTC makes  
18 sure that the specialty pharmacies are not using those  
19 cartridges for a generic. Once UTC is comfortable that the  
20 specialty pharmacies are only using it for Remodulin®, then  
21 UTC will sell them the cartridges.

22 THE COURT: Who owns those cartridges?

23 MR. GLASS: UTC does.

24 THE COURT: And how about if UTC says we'll sell you  
25 these cartridges, but as double what the market price has?

1 MR. GLASS: Your Honor, I don't want to speak for my  
2 clients, but I'm sure they would take that. I -- I have no  
3 doubt that my client would buy cartridges from UTC at a hefty  
4 premium to what UTC paid for them.

5 Your Honor, again, I haven't consulted with my client.

6 THE COURT: You want to go back in the conference  
7 room?

8 MR. GLASS: I mean, Your Honor, it shows you how  
9 important the cartridges are. I don't want to negotiate for  
10 my client, but I'm not sure there's any number you can tell me  
11 today that I wouldn't take back to my client and we would have  
12 a very serious discussion of paying that.

13 Now, Your Honor, the balance of harms and important  
14 part -- and this goes to irreparable injury in a very unique  
15 way for this case. There is an irreparable injury to the  
16 public as well. So this normally goes under the public  
17 interest prong. The public interest prong is normally a  
18 throwaway in preliminary injunction cases that's tacked on to  
19 the end. Here, the public interest prong is paramount. The  
20 public interest is in having access to all of the competing  
21 drugs. That is undisputable. The public has an interest in  
22 being able to choose between the Remodulin® product and  
23 plaintiff's generic product. The public has an interest in  
24 the competition that the generic product brings to Remodulin®.

25 THE COURT: Well, the public interest isn't that they

1 can't get the drug because clearly there are -- they're  
2 getting the drug, albeit at a higher cost, perhaps. And there  
3 are three other methods that they can get the drug, albeit not  
4 the preferred method of having the drug administered, correct?

5 MR. GLASS: Respectfully, Your Honor, no.

6 THE COURT: Okay. Tell me why.

7 MR. GLASS: Let me start with, yes, patients can get  
8 access to Remodulin®. There is no dispute that patients can,  
9 at a 98 percent margin.

10 THE COURT: Okay.

11 MR. GLASS: So in the annual report -- if Your Honor  
12 will please turn to slide 12. In UTC's annual report, it  
13 states exactly how much revenue and profit it gets from  
14 Remodulin®. \$599,000,000 in revenue on 584.9 million in  
15 profit.

16 THE COURT: Okay.

17 MR. GLASS: What would happen is patients and payers  
18 would significantly benefit from the entry of a generic  
19 because that gross profit number, even if Remodulin® kept all  
20 100 percent of its patients, would go down.

21 How do we know that? Because on slides 13 and 14, we  
22 have evidence from discovery on what the response was by the  
23 mooted, just the mere threat of RareGen and Sandoz entering.  
24 So this is the part where we've agreed with the defendants not  
25 to say in open court.

1 THE COURT: Okay.

2 MR. GLASS: But you can see from this testimony, this  
3 is the president of UTC. The president of UTC testified that  
4 they increased price in 2018, and they decreased price in  
5 2019. And the factor for decreasing price instead of  
6 increasing price was the mere shadow of us entering.

7 So that's where the public would benefit is again going  
8 back to that \$585,000,000 in profit, if that went down, that  
9 money doesn't come to us. That money goes to the public.

10 THE COURT: Right. And again, just so I'm clear, the  
11 public is still getting this drug, albeit at a higher cost.  
12 It's not like the drug isn't available. And if they can't get  
13 the drug through this method of administration, there are  
14 other ways that it can be administered, albeit not the  
15 preferred way.

16 MR. GLASS: Right. So I'll address the oral and pill  
17 in one second, Your Honor.

18 THE COURT: Right.

19 MR. GLASS: So access -- we don't have any evidence  
20 that patients who need PAH treatments aren't getting access.  
21 So I want to tell Your Honor we've had very limited discovery.  
22 So we don't have that evidence. But I will tell Your Honor  
23 that there are patients who cannot afford the drug. This  
24 happens in every case where when the generic enters, the  
25 number of patients on the treatment expands.

1 THE COURT: Okay.

2 MR. GLASS: The reason why is that when you have a  
3 brand -- and I'm not good at math so I won't do the math for  
4 you. But you can divide the 600,000,000 in revenue by the  
5 number of patients to see what the cost is per treatment, per  
6 patient.

7 THE COURT: Okay.

8 MR. GLASS: Part of that is paid for by insurance  
9 companies. Part of that is paid for by the patients  
10 themselves.

11 We know that there are patient assistance programs that  
12 help lower means, patients, to get access to the drugs. In  
13 fact, UTC has a patient assistance program, it's on slide 14,  
14 that when we were even threatening to enter, they improved the  
15 benefit on the patient assistance program by a hundred  
16 percent. They cut the amount that the patients had to pay out  
17 of their own pocket.

18 But there are two important things to note. It's still  
19 not zero, and there are patients who cannot even afford the  
20 amount that the patient assistance program offers. And there  
21 are patients who UTC deems counteracts as the patient  
22 assistance program and don't get the benefits. So I don't  
23 want to represent that we've got evidence from discovery  
24 because it's been limited. But I will tell Your Honor that in  
25 the generic cases, which I've litigated many of, as have my

1 co-counsel, when the generic enters the number of patients  
2 covered by the treatment expands, that expansion are patients  
3 who are today unable to get on the preferred treatment. Okay.

4 Now I'll do the three other routes. I really want to  
5 address your question on the three other routes. What does  
6 that mean for those patients? Well, it's possible that  
7 they're going untreated, but it's unlikely.

8 THE COURT: Okay.

9 MR. GLASS: The more likely is that they're being  
10 treated by a less preferred drug. It could be one of the  
11 other three routes. So there's intravenous, there's oral, and  
12 there's inhaled. It's possible that some of those patients --

13 THE COURT: And they all are either not as effective  
14 or bring other inherent risks to the patient rather than this  
15 type of delivery?

16 MR. GLASS: Exactly, Your Honor. So a physician, not  
17 us, not UTC, makes the determination which route of  
18 administration is best for that patient. And it's patient by  
19 patient. There are some patients that just -- inhaled works  
20 best. There are some patients that can't tolerate the pain of  
21 injections. There are some patients who are so sick that  
22 inhaled and oral just doesn't work.

23 And so this is a physician decision. So the physicians  
24 are making the treatment decisions based upon what's best for  
25 the patient. The position the defendants are taking is that a

1 physician can't prescribe the preferred route of  
2 administration for a particularly sick patient and must  
3 prescribe oral or inhaled if they want a lower price. And  
4 that's just not right. It's not right. Physicians should be  
5 free to prescribe the best administration for the patients.  
6 And the physician shouldn't be put in the very difficult  
7 position of saying, I'm asking the patient to pay more than  
8 they should or the insurer to pay more than they should, and  
9 therefore I'm going to have them do a less preferred.

10 Even between IV and subcutaneous, there is very little  
11 switching. So on slide 15, we have testimony from the  
12 president of UTC. He testified that there's very little  
13 switching from IV to subQ. He testified the more likely is  
14 the other way around, subQ to IV. And it makes sense. There  
15 are a lot of downsides to subQ and would only be if the  
16 patient really needs it. Most importantly there's a lot of  
17 site pain. There are also a lot of downsides to IV. Most  
18 importantly, sepsis, a deadly condition. So physicians make a  
19 determination on what's the best drug and what's the best  
20 route of administration.

21 And if I may, Your Honor, the argument the defendants  
22 make that PAH patients have all kinds of other ways they can  
23 be treated, it just really doesn't help in an antitrust case.  
24 In an antitrust case we don't consider every possible  
25 substitute. We only consider reasonable substitutes. So in

1 this case, it wouldn't be enough that bed rest would help a  
2 PAH patient. That doesn't make it a substitute. It's not  
3 enough that some PAH patients benefit from aspirin. And it's  
4 not enough that some PAH patients are currently untreated or  
5 are on oral, IV or inhaled. Since the doctors would put them  
6 on subcutaneous, and that's where they would get the distinct  
7 benefit of our competition.

8           It's not just subcutaneous where they benefit from our  
9 competition, though. IV patients benefit from our competition  
10 once we get cartridges. I'm going to take a second because  
11 this is a little hard to explain. We're currently offering  
12 IV. Plaintiffs offer IV. However, to get on the formulary  
13 for the insurance companies, and get the insurance companies  
14 to say must substitute, and to get prescribers on board with  
15 the generic, we also have to be on subQ. We have evidence of  
16 that. We've put it in as a declaration, but it's in slide 16,  
17 that our entry, even into IV has been muted because of our  
18 inability to provide a subcutaneous option.

19           Physicians do not want to have to say, oh, the  
20 Remodulin® substitute is only built for IV because they just  
21 want to be able to prescribe generic or not.

22           Insurance companies are about simplicity and  
23 efficiency. They don't want to have to determine whether or  
24 not a person is prescribed for subQ for IV or whether they're  
25 prescribed for subQ or IV based upon some other sort of



1 payment avoidance. So they've told us that we will not go on  
2 a repertory -- we will not go on a formulary until we have a  
3 subQ available product. And so Your Honor, we're being  
4 blocked not only from subQ, but really from IV as well.

5 Now, defendants have said we've brought all this on  
6 ourselves. That we should have done more diligence. I've  
7 already discussed with Your Honor that we didn't know this  
8 would be a problem until the beginning of this year.

9 Defendants have also said, well, you shouldn't have  
10 launched an IV. But that also says that we shouldn't provide  
11 any patients with a lower cost alternative. That was not  
12 palatable to Sandoz and RareGen. Sandoz and RareGen launched  
13 an IV so that at least some patients could get the benefit of  
14 choice. Even if it was imperfect and even if it was muted, we  
15 were not going to hold back our IV product just to make this  
16 case better. Just to be able to tell Your Honor that we have  
17 a great preliminary injunction. Not even to preserve 180-day  
18 exclusivity.

19 So this is really about patients. We're trying to  
20 serve patients. We're trying to get that profit down, which  
21 is a return directly to patients in the healthcare system.

22 And, Your Honor, I know my time is getting short, so I  
23 won't spend too much time on this, but that is exactly what  
24 defendants are worried about. If we come on the market and we  
25 compete with them, they will lose the Remodulin® franchise,

1 which would be devastating. And you know what? I don't blame  
2 them. It's been a great run. They had patents. They're  
3 making 98 percent profit. They're charging whatever they  
4 want. They're able to put in their annual reports that  
5 they're making almost 600 million dollars. But, Your Honor,  
6 the patent is over. They cannot use the anticompetitive  
7 conduct to extend the patent. They can't continue to block  
8 the generics from being able to approach this patient  
9 population.

10 But as you'll see in the slides that start my  
11 presentation, that's exactly what they intended to do, and  
12 that's exactly what they did. And the way that they did was  
13 despicable. They went to the specialty pharmacies, and they  
14 told the specialty pharmacies you will not get any more  
15 cartridges until you sign these exclusivity agreements.

16 So Your Honor asked why, you know, we don't have  
17 specialty pharmacies or insurers or patients as parties here.  
18 Because none of them have done anything wrong. It's a hundred  
19 percent the conduct of defendants that have blocked us from  
20 this market. They did so by threatening to withhold  
21 cartridges, which the president of UTC admitted -- on slide  
22 4 -- was negotiating leverage to get the specialty pharmacies  
23 to sign the contract that blocked RareGen and Sandoz. And it  
24 worked. Because in May and late April of this year, after we  
25 filed our case, CVS and Accredo signed the contracts saying

1 they will not dispense cartridges outside of Remodulin®, thus  
2 blocking us completely from the market.

3           So Your Honor, I implore Your Honor -- first, I thank  
4 Your Honor for the time that Your Honor's giving us today as  
5 well as providing us with discovery because virtually  
6 everything that we alleged in our complaint is true. But it's  
7 true to a more extreme than we ever thought. We never thought  
8 that the defendants would risk patient lives by withholding  
9 cartridges. We never thought that they would force the  
10 specialty pharmacies to do something they didn't want to do,  
11 and the only reason that the specialty pharmacies acquiesced  
12 is because they couldn't go out of cartridges and thus leave  
13 their own patients at risk.

14           We had no idea that Mr. Benkowitz and the witnesses in  
15 this case would be so candid and tell us exactly what was  
16 going on, and we had no idea they would have documents within  
17 UT Smiths that shows that this was all designed to block us  
18 from entering the market.

19           So Your Honor, thank you for providing us with  
20 discovery and the time today. What I would tell Your Honor is  
21 that the clock is ticking. We really need access to these  
22 cartridges, but more importantly, the public needs access to  
23 these cartridges. Thank you, Your Honor.

24           THE COURT: Thank you.

25           MR. PITT: Your Honor, may I approach to hand up --

1 THE COURT: Please.

2 THE DEPUTY COURT CLERK: Thank you.

3 THE COURT: So if you're just looking at this from  
4 afar, and you go back in history and there was the lawsuit  
5 that ultimately was resolved and the resolution was the  
6 generic can come to market at such-and-such a time. And  
7 meantime, there's this event that occurred, and you're buying  
8 up the means to which the generic can go to market.  
9 Optically, how does that work?

10 MR. PITT: Well, Your Honor --

11 THE COURT: The way I said it.

12 MR. PITT: Respectfully, the way you said it, Your  
13 Honor --

14 THE COURT: Doesn't look good.

15 MR. PITT: -- is not actually what occurred.

16 THE COURT: I'm just saying the way I said it doesn't  
17 look good optically.

18 MR. PITT: If out of nowhere --

19 THE COURT: There was a nefarious plan --

20 MR. PITT: -- not proceeded by any other  
21 arrangements, which they're trying to say the world started in  
22 late 2018.

23 THE COURT: Right.

24 MR. PITT: The world started far before then with the  
25 arrangements that my client, United Therapeutics, put into

1 place to ensure that their patients would have adequate pumps  
2 and cartridges when they learned that Smiths was discontinuing  
3 those items.

4 THE COURT: I guess your position is we had enough  
5 foresight to look forward to see what was going to happen. We  
6 wanted to protect our patients, so we fought the world and our  
7 patient's protected.

8 MR. PITT: Not exactly, Your Honor. It's not that we  
9 had some clairvoyant power to know what was going to happen in  
10 the future.

11 THE COURT: They told you what was going to happen.

12 MR. PITT: They told everyone what was going to  
13 happened. Sandoz indisputably was on notice. The  
14 instances -- and why don't I just go right to it. The  
15 instances of Sandoz being on notice are many. 2011 when they  
16 filed their ANDA, they expressly note that they need a  
17 cartridge reservoir for the drug in order to inject it  
18 subcutaneously.

19 Three years later, 2014, they receive tentative  
20 approval so they know they're going to launch the drug. What  
21 do they do at that time? Nothing.

22 2015, the following year, they settle the patent  
23 litigation, and they know there's an agreed entry date of June  
24 26th, 2018.

25 The agreement, by the way, Your Honor, also has a

1 provision that expressly says that nothing in the agreement  
2 gives Sandoz any right to any pump or delivery system by a  
3 third party or by United Therapeutics. That's directly in the  
4 agreement.

5 It's undisputed that --

6 THE COURT: At that point the world knew what was  
7 happening with the pump and the cartridge.

8 MR. PITT: Well, certainly the customers did who had  
9 received the end of life notice. And certainly Sandoz did  
10 right after then.

11 2016, this email is by Yaping Zhu who -- Dr. Zhu is, I  
12 believe, the Senior Director of Device Development at Sandoz.  
13 And this email is to the leaders of the product launch. It  
14 can't be disputed that Sandoz was on notice after having  
15 signed that Hatch-Waxan lawsuit settlement.

16 On the topic of Hatch-Waxan, I think it's important to  
17 note a couple of things, just in response to what we've just  
18 heard. First, Your Honor, Hatch-Waxan applies very  
19 specifically to the drug. It provides no access to delivery  
20 mechanism, technology, or anything else. It's all about the  
21 drug.

22 THE COURT: Understood.

23 MR. PITT: And everyone who plans to launch a high  
24 touch drug like this, and wants to be able to launch it to a  
25 patient population that will be -- will have it administered

1 subcutaneously knows there is a lot of work to do to ensure  
2 that there is a delivery system in place. That is the work  
3 that my client did to ensure that its patients -- that there  
4 would be enough cartridges for its patients to use.

5           And now the plaintiffs come along and say, well, the  
6 world actually started in 2018. None of this stuff was here  
7 before. I can show you why that's wrong, Your Honor, and why,  
8 in fact, the provisions that they are complaining about today  
9 have always been aspects of the agreement, which was always an  
10 exclusive arrangement with Smiths whereby Smiths would produce  
11 cartridges they wouldn't otherwise have produced. Wouldn't  
12 have the charges here today to fight over if United  
13 Therapeutics hadn't made the upfront investment and assumed  
14 the risk, very importantly, for an activity that Smiths wasn't  
15 willing to continue to engage in. We did those things with  
16 the expressed understanding -- and the contemporaneous  
17 evidence all supports this -- we did those things with the  
18 expressed understanding that, of course, they would be for our  
19 patients.

20           THE COURT: When does being forward-thinking, good  
21 business sense, you becoming worried about your supply to  
22 service your patients, when does that cross the line and  
23 become anticompetitive conduct? Not in this case, you're  
24 going to say.

25           MR. PITT: I was just going to say some place beyond

1 what we've seen here.

2           Your Honor, there is evidence, and we've submitted it,  
3 that demonstrates that our client has forecasts of -- and to  
4 be clear, in the past, every time we've had forecasts about  
5 the burn rate of these cartridges, we have undershot that burn  
6 rate significantly. All of these additional instances of  
7 cartridge production are generally for two reasons. One is we  
8 did not -- we thought cartridges would be used more slowly  
9 than they were, but they fluctuate wildly, the use -- the  
10 extent of the use does fluctuate. And number two, all of what  
11 you -- what you see in these agreements is also reflective of  
12 the fact that people other than generics are trying to get  
13 these cartridges.

14           THE COURT: There was a point made that you didn't  
15 know where the cartridges were going. They were being used  
16 for delivery of other medications.

17           MR. GLASS: For antinausea medication, 88,000  
18 cartridges. RareGen itself tried to do a bulk purchase in  
19 January 2019 of 300,000 cartridges. There are reasons why my  
20 client wanted to ensure that the original deal it struck,  
21 which involved having enough cartridges for its patients for  
22 an extended period of time because you need belt and  
23 suspenders. You need to be able to plan. You can't always  
24 know exactly when the next generation technologies are going  
25 to come online, and you can't always predict what the



1   fluctuations will be in the patient's use of the cartridges.  
2   And for all of those reasons, we set about ensuring that we  
3   would have a steady supply. What they want to do now is say  
4   we did none of that. And they say, well, we were bamboozled.  
5   We think actually what happened was the specialty pharmacies  
6   told us they could do it, but then they couldn't. But if you  
7   look closely, you'll see that they never asked about  
8   cartridges until January 2019 was the first time they asked  
9   about a supply of cartridges.

10           By the way, in early 2017, Your Honor, Sandoz wanted to  
11   test its drug. They tried to obtain just two pumps and two  
12   cartridges, and they were unable to do it. They were unable  
13   to do it because they weren't being sold on the market  
14   commercially because they had been discontinued. Again, they  
15   say they had no notice, but event after event after event  
16   demonstrates that they did.

17           So finally, in January 2019, they asked the question  
18   and they're told in no uncertain terms there are no cartridges  
19   for you because there is this exclusive arrangement. Those  
20   cartridges are for United Therapeutics customers.

21           THE COURT: So let's walk outside this courtroom now  
22   and talk about the argument that counsel made that there are  
23   real people out there that have issues that need this drug  
24   that may not be able to afford this drug, and by keeping them  
25   out of this market, you're either depriving them of a

1 preferred method of delivery or they're not getting any drug.

2 MR. PITT: There is zero evidence of that, Your  
3 Honor, and, frankly, it is simply not the case. First of all,  
4 the figures that they are using on price are -- the discounts  
5 and the like, that's not price paid by patients. That's  
6 prices paid by payers, and those are decisions that go  
7 through -- they talk about -- by the way, in describing their  
8 alleged reputational harm, they talk about the specialty  
9 pharmacies won't trust us, the prescribers won't trust us,  
10 insurers and payers won't trust us. Zero evidence of any of  
11 that in the record. Absolutely nothing in the record on any  
12 of that. They had additional depositions left over. They  
13 complain that they had limited discovery, but they had  
14 additional depositions they didn't use. For all the emphasis  
15 that they've placed on the importance of specialty pharmacies,  
16 the claim that they were threatened, which is absolutely not  
17 supported --

18 THE COURT: You say this is a money damage case?

19 MR. PITT: I'm saying it's not an antitrust case  
20 because there's no cause of action for a variety of reasons.  
21 But to the extent that one day they could demonstrate  
22 liability, then for a number of reasons, yes. Number one,  
23 what they're claiming would be compensable by monetary  
24 damages, which the cases clearly reflect. Number two, no  
25 evidence of any of what they're now claiming would occur, only

1 speculation by some of their own employees that they are  
2 worried that that kind of thing might occur.

3           You know, the -- there is even testimony from the  
4 plaintiffs in which they concede that an injunction wouldn't  
5 remedy the reputational harm that they're now claiming. But I  
6 want to actually get to another point about irreparable harm,  
7 if I may, unless you want to stay on that topic.

8           THE COURT: I'm curious. Counsel brought up an  
9 interesting point about the 180-day exclusivity. So they've  
10 lost that. How is that calculable? How is that repairable?

11           MR. PITT: Well, first of all, it's not something  
12 that they can recover for because it is self-inflicted. I say  
13 that for two reasons. The first is they did make a choice.  
14 They now have all kinds of explanations about why they did,  
15 but it is undisputed that they made a choice. There is a  
16 slide which I'm not going to show because of our agreement  
17 with counsel, but I would ask you to look at slide 15, which  
18 is a table in which Sandoz and RareGen were debating, well,  
19 what should we do and what are the financial consequences of  
20 that? And they ultimately made a decision to go for -- I know  
21 they put everything in terms of the patient, the patient, the  
22 patient. They are not nonprofit companies. They are  
23 interested in making a profit, and in that case they were  
24 interested in the short-term gain that this would afford them  
25 rather than waiting until they solved their cartridge problem

1 before launching.

2           The 180-day exclusivity would also have waited for  
3 them, but they made the decision to launch. And I don't see  
4 how they can now claim that that is irreparable harm that is  
5 compensable. In connection with that point, Your Honor, the  
6 following slide 16 here demonstrates that at the time they  
7 made that decision, that expressly acknowledged that if they  
8 went with the intravenous only plan, it would result in payers  
9 not mandating generic substitution the harm they're now  
10 claiming they're suffering. They knew all of this before they  
11 made the decision, but now they want to call it irreparable  
12 harm and say that it is somehow appropriate to upset what has  
13 been a nearly four-year arrangement for a supply that we have  
14 relied on and continue to rely on. It's simply not the case  
15 that we wouldn't be harmed if all of a sudden Your Honor were  
16 to say those cartridges that you invested in and that you  
17 assumed the risk to have made and that you have always had an  
18 understanding with Smiths were for your patients and that  
19 you've built your business plans around and your distribution  
20 chain, those are now going to be given -- or some number of  
21 them are now going to be given to another company, of course  
22 we would be harmed, Your Honor.

23           THE COURT: When you say "your patients," though,  
24 clearly when you were the only drug on the market, they were  
25 your patients. But now that there could be other drugs on the

1 market, don't your patients have a right to say I'd rather  
2 have a generic rather than a branded?

3 MR. PITT: Well, the patients may or may not have  
4 that right, Your Honor, but when the company that is making  
5 the generic drug is repeatedly on notice of the need to  
6 provide an administration mechanism and doesn't do it, the  
7 fact that some patients aren't able to get the generic for a  
8 certain kind of administration is not at our doorstep. And  
9 the antitrust laws don't permit a competitor who is not an  
10 equally efficient competitor to come in at the last minute and  
11 sort of say, well, gee, we need what they have. They planned  
12 for it, but we need it so now we want you to order it given to  
13 us. That's simply now how they work.

14 The -- just a couple of other points to touch upon some  
15 things we heard. Obviously, if Your Honor has other  
16 questions -- I also wanted to mention that Mr. Boyle, who  
17 represents Smiths, may want to also say a few words. And we  
18 only have kind of one time to stand up here, so I want to make  
19 sure that if I'm starting to push the limits of what Your  
20 Honor had in mind in terms of time, that we give Mr. Boyle  
21 some opportunity as well.

22 But just a couple of other points. They -- again, I  
23 would say that the -- that the alternatives that have been  
24 available to them are something that we haven't heard a lot  
25 about. But one of the reasons why it's so critical to note

1 that in that -- in that whole seven-year period of time when  
2 the plaintiffs were repeatedly on notice of the need to  
3 provide for this, what could they have done? Well, they could  
4 have done any number of things. They could have done what  
5 they ultimately wound up doing in May of 2019 and contracted  
6 with somebody to start manufacturing a cartridge. They claim  
7 they weren't aware of that. But the fact is, Your Honor, they  
8 had no arrangement, no agreement, no contract with somebody --  
9 a specialty pharmacy or otherwise -- to manufacture a  
10 cartridge for them, no written commitment of this supply.  
11 This particular supply is yours, and your patients will have  
12 access to it. None of that until in May of 2019 they finally  
13 contracted with a company -- whose name I've agreed not to  
14 state in open court -- but they've contracted with a company  
15 who then, in a matter of just a few months, was able to  
16 produce a prototype. We have no visibility into why they  
17 haven't yet sold it. We asked -- all of the documents suggest  
18 that September or October was the date in which that was to  
19 occur. We have not -- we've asked for some discovery of that  
20 and they've not given it to us, so we don't really have any  
21 visibility into why now they have not yet sold it. But we do  
22 know they had also sought to make arrangements with another  
23 company. Again, I won't mention the name here. And they  
24 ultimately sent a breakup letter to that company saying we're  
25 not interested. We're going with this other company.

1           The cost for these things, by the way, developing a  
2           prototype was cited at around \$50,000. We're not talking  
3           about a huge cost. If you'd like to see what a cartridge  
4           looks like, it's this. This is the cartridge that we are  
5           fighting over today.

6           I want to talk just briefly about the fact -- the sort  
7           of world not starting in late 2018 point. By the way, also  
8           many options, before I get there, of pumps, that the ability  
9           -- both experts in this case agree you can customize --

10           THE COURT: What was your company doing prior to this  
11           product coming on the market as far as delivery?

12           MR. PITT: As far as prior to the CADD MS®3 coming on  
13           the market?

14           THE COURT: Yes.

15           MR. PITT: I believe we believed we used the MiniMed.  
16           There was another pump that we used called the MiniMed, and  
17           that pump is still being used, I believe, in other countries.  
18           Could be cleared, if one wanted to try to go through the  
19           process of clearing it through the FDA, could be cleared again  
20           for use in this country.

21           The MS®3 itself, by the way, used to be an insulin  
22           pump. It was modified essentially with some software  
23           modifications so that it was capable of dispensing Remodulin®  
24           subcutaneously. That's what Smiths did. That's how they got  
25           the pump originally. Both experts in this case have agreed

1 that to do that now would involve a time period of 12 to 24  
2 months. They both agree it could be done in that time period  
3 of a cost of around one-and-a-half to three-and-a-half million  
4 dollars. Frankly, all of which is a pretty small fraction, if  
5 you look at the following slide, which I'm not going to show  
6 in open court.

7 THE COURT: 22?

8 MR. PITT: Yes. It's a small fraction of what it  
9 would have cost or, rather, what the parties believed or what  
10 the plaintiffs believed they were going to make in just their  
11 first year of operation here.

12 On the point, Your Honor, of whether the world started  
13 in late 2018, I don't need to go through all of this because  
14 it's -- it is in our papers, Your Honor, but I do want to be  
15 clear that the contemporaneous evidence strongly supports the  
16 fact that this agreement has always been an exclusive  
17 arrangement between Smiths and United Therapeutics. There  
18 were amendments along the way when various things happened,  
19 when we saw cartridges flying off the shelves and we realized  
20 we needed to do something in order to honor the purpose and  
21 effect of that original agreement. But the agreement has  
22 always involved exclusivity.

23 You know, a quick word, I guess, on the public interest  
24 and on -- well, I guess really on the public interest in  
25 particular.



1           Again, I've already discussed the fact that there is no  
2 evidence that any patient is being harmed. In fact, their own  
3 employees testified that no patient is being deprived of any  
4 drug. There is no evidence in the record that any patient is  
5 actually even paying more. There is evidence about the  
6 pricing to specialty pharmacies, not to patients.

7           The public interest is not furthered when companies are  
8 disincentivized from having foresight and making investments  
9 and assuming risks in order to prepare for their future needs  
10 and then know that they will risk having another company,  
11 their competitor, direct competitor, come along and simply  
12 strip them of the fruits of their investment. That does not  
13 serve the public interest, Your Honor.

14           We've got a number of other points in our papers, but I  
15 think at this point I've really covered most of what I was  
16 intending to cover with Your Honor, but I'm glad to answer  
17 further questions or else to turn things over to Mr. Boyle to  
18 make the points that he was interested in making.

19           THE COURT: Okay.

20           MR. PITT: Thank you, Your Honor.

21           THE COURT: I think you have about nine minutes.

22           MR. BOYLE: Thank you, Your Honor. Peter Boyle for  
23 Smiths Medical. I just want to make a few points.

24           Smiths has been trying to wind down the MS®3 product  
25 line for five years now. The reason it's in the middle of

1 this case is because it did the right thing for patients by  
2 entering into a supply arrangement with United Therapeutics to  
3 extend production on both the MS®3 pump and the MS®3  
4 cartridge.

5 To be clear, the pump is discontinued. Smiths stopped  
6 making that product and selling it in 2017. The cartridges,  
7 which now seem to be the focus of this case, those products  
8 would not exist today but for the arrangement with United  
9 Therapeutics and Smiths.

10 Counsel for plaintiffs made reference to our  
11 end-of-life notice for the pump. That went out in August  
12 2015. They want to act like that notice did not tell  
13 customers what was going on with cartridges at that time. If  
14 you look at the end-of-life notice, Smiths told customers in  
15 August 2015 that cartridges would be available for around  
16 another three years. We submitted a declaration from Carl  
17 Stamp in connection with these proceedings. Mr. Stamp was  
18 head of marketing and business strategy at Smiths back in  
19 2015. He clearly states in his declaration, in the absence of  
20 the UT arrangement with Smiths, Smiths would have stopped  
21 making those cartridges some time in 2018. They would not  
22 have been available for the generic launch of this product.

23 One of the positions that plaintiffs have taken with  
24 respect to the cartridge is the margins on the cartridge --  
25 the gross margins were so high that in some gerrymandered

1 but-for world, Smiths would've just kept making these products  
2 indefinitely. That's not true. Smiths had already decided to  
3 discontinue this product.

4 We have evidence from Chris Quinn. We submitted a  
5 declaration from him. And Nate Walker has -- who is one of  
6 our global product managers -- gave a deposition. If you look  
7 at those pieces of evidence, Your Honor, you'll see Smiths was  
8 not going to continue making these products.

9 Just to put this in perspective, in fiscal year 2019,  
10 that ended in July, Smiths only made about \$500,000 in  
11 revenue. That's top line revenue -- not profit -- on the  
12 cartridges. I mean, we seem to be talking about hundreds of  
13 millions of dollars, and plaintiffs are suggesting they, they,  
14 they are going to make all this money. Smiths isn't making  
15 that type of money off of this product.

16 To continue the cartridge production, Smiths and  
17 plaintiffs point to this evidence. Smiths would have had to  
18 retool the mold. That's a \$300,000 expense. They would have  
19 had to qualify new resin. That's about a \$220,000 expense  
20 that the record shows.

21 So if you compare that to the revenues Smiths was  
22 making off of this product, the economics don't make it worth  
23 the while of Smiths to continue making the product but for the  
24 investment by United Therapeutics.

25 Now, if you look at the record, it is clear Smiths did

1 not try to keep a generic off the market in this instance. In  
2 2016, it told Sandoz two or three times that MS®3 was going to  
3 be discontinued. In fact, one of our people told Sandoz that  
4 it doesn't make sense to bring a new drug to market on the  
5 back of a discontinued product. Sandoz ignored us. They went  
6 forward anyway. They took the position, we're a drug  
7 manufacturer. Devices are not our problem.

8 In 2019, when they found out they really had a problem,  
9 they came back to Smiths. Now, at that time all the cartridge  
10 production that was still available was contractually  
11 committed to United Therapeutics. It had been committed years  
12 before. But even though Smiths could not sell cartridges to  
13 the plaintiffs, it tried to help them. It offered them the  
14 CADD legacy pump. That's the pump that's used for IV infusion  
15 of Remodulin®, Your Honor. It has subcutaneous functionality.

16 Smiths also offered to license the cartridge  
17 technology, help them figure out the product specifications,  
18 know-how around product development and product manufacturing.  
19 They turned that down. We can't help that.

20 One thing is really clear. Smiths did not take any  
21 action here that kept this generic off the market. This is  
22 not an antitrust problem. Whatever problem it is, it's not an  
23 antitrust problem.

24 The one thing I will say, just to follow up on what Mr.  
25 Pitt said in response to plaintiff's counsel's argument, there

1 seems to be some suggestion here that the plaintiffs are  
2 really taking it on the chin in terms of price. Our economist  
3 in his expert report has some facts in there that show that in  
4 this environment, the brand of generic are being reimbursed by  
5 payers, Medicare, Medicaid payers, at the same rate.

6 They also have a slide in here on page 14 of their  
7 slide deck showing that the brand actually lowered the amount  
8 of co-pay for the patient. So we actually may be in a  
9 situation now where the patient today may be paying less for  
10 the brand than the generic.

11 So that is one final point. So with that, Your Honor,  
12 for defendants, we'd just ask that you deny the preliminary  
13 injunction. We also urge Your Honor to take a look at our  
14 motion to dismiss and grant that as well. If there are no  
15 further questions or any questions --

16 THE COURT: No. Thank you.

17 MR. BOYLE: Thank you.

18 MR. KENT: Good morning, Your Honor.

19 THE COURT: Welcome.

20 MR. KENT: Matthew Kent from Alston & Bird on behalf  
21 of the plaintiff Sandoz Inc. PowerPoint seems to be very  
22 popular today, so I have one to provide you as well.

23 THE COURT: Okay.

24 MR. KENT: Your Honor, the argument that Sandoz and  
25 RareGen were not diligent is nothing but an effort and

1 misdirection to misdirect this Court away from the defendant's  
2 conduct in this case from their efforts to block patients from  
3 a cheaper generic alternative. And there are two points that  
4 I want to walk the Court to that are specifically responsive  
5 to some of your questions that you posed to defendant's  
6 counsel as well as Mr. Glass.

7           First, I'm going to walk through the evidence that  
8 shows that Sandoz and RareGen were diligent in pursuing their  
9 launch of treprostinil. And second, I'm going walk through  
10 the timeline because I think it's critical that the Court  
11 understands when these restrictions were put in place because  
12 it shows that the free-riding argument that the defendants are  
13 setting forth doesn't make sense. It shows that the fact that  
14 the cartridges were not actually restricted at all for  
15 specialty pharmacies before 2019, it's something we actually  
16 agree on, and it also shows that the purpose and the intent of  
17 these arrangements was to block generic competition.

18           So let's start with Sandoz and RareGen's diligence.  
19 Now, I understand the diligence story. Your Honor correctly  
20 got to the crux in the initial questions that you were asking  
21 Mr. Glass. We have Sandoz and RareGen who produce the drug,  
22 and their customers, they are the specialty pharmacies. The  
23 specialty pharmacies here, they're the ones that provide the  
24 drug to patients, and they have always provided the cartridges  
25 and provided the pumps to patients.

1           And so when we think about the launch here, Sandoz and  
2 RareGen did exactly what you would expect a company to do.  
3 They went and they spoke to their customers at Accredo, and  
4 they asked them, what do we need to provide? And we see in  
5 August of 2017, on Exhibit 906, that Accredo confirmed -- I  
6 have it highlighted in yellow -- Accredo expects Sandoz to  
7 provide treprostinil vials only. And that's critical. That's  
8 diligence. Sandoz was going to its customers and it was  
9 asking, what do we need to provide, and it got an answer.

10           They also did the same thing with CVS. We did not cite  
11 this particular presentation in our brief, but Exhibit 907 is  
12 a CVS presentation that talks about how CVS SP will procure  
13 the pumps.

14           RareGen did the same thing. It talked to Accredo. It  
15 sent emails in May of 2018. That's Exhibit 314. It asks  
16 whether or not Accredo would have to provide pumps and  
17 cartridges or whether they, RareGen, would have to come up  
18 with those. And Accredo responded no. We handle the pumps.

19           THE COURT: Well, at that point, does your client  
20 know what's going on with Smiths?

21           MR. KENT: Well, Your Honor, I think this is a great  
22 effort at a sleight of hand in this direction because this is  
23 not a problem with the pump. So counsel for the defendants,  
24 they keep talking about the end-of-life notice that was sent  
25 in 2015 by Smiths, but that is an end-of-life notice for the

1 pumps. It is undisputed that that did not relate to  
2 cartridges. And, in fact, when you look at that end-of-life  
3 notice, you'll see that it talks about the cartridges being  
4 made for many years in the future. And in fact, we saw in the  
5 marketplace that the specialty pharmacies, Accredo and CVS,  
6 were able to continue to supply pumps and cartridges to  
7 patients. There was no reason for Sandoz and RareGen to think  
8 that UTC would use coercive, extreme measures to try to get  
9 those specialty pharmacies to agree to those restrictions.

10 And Mr. Glass didn't have a chance to go through, but  
11 if Your Honor would look at slide 3 of the PowerPoint  
12 presentation that Mr. Glass had, it has some of the salacious  
13 statements that the specialty pharmacies were going through.  
14 We're in serious need of product and will not be able to  
15 service our patients. This will have a significant impact on  
16 our patients. This is a huge risk to the patients. They were  
17 withholding cartridges that are needed, lifesaving medicines  
18 that are needed for patients in order to extract efforts to  
19 block the generic.

20 And I'll tell Your Honor, the most clear evidence of  
21 that blocking is cited in our brief. It's Exhibit 475. And  
22 it's on page 16 of our papers. It says, "We have a contract  
23 amendment from UTC that requires us to only sell to MS®3  
24 cartridges to UTC designated customers. It is very important  
25 to UTC to prevent generic drug users."



1           And that's precisely what's happened. They have  
2 blocked generic drug users by creating a restriction so that  
3 specialty pharmacies cannot use those cartridges for patients  
4 with generic treprostinil.

5           I want to show one thing that we do agree on which is  
6 the timeline. It is undisputed in this case that Sandoz and  
7 RareGen didn't know of the cartridge restrictions until  
8 January of 2019. And let's put up the timeline. There are a  
9 lot of agreements in this case, Your Honor, and in fact, in  
10 reading the statement of facts, it can be hard to follow. So  
11 we created a timeline of these agreements.

12           Now, the defendants want you to believe that with the  
13 end-of-life notice that they were somehow diligent and that  
14 they came up with a path forward and were, in essence, free  
15 riding. That is simply not the case. The end-of-life notice  
16 came out before the first agreement was entered into. But  
17 ultimately, these agreements are not the most important ones  
18 in this case because they relate to pumps.

19           Now, if you go to the next slide, each of the  
20 agreements that I've marked an X over, they don't restrict the  
21 cartridges. The cartridge restrictions were not even done in  
22 January of 2019. They were done in April and in May of 2019.  
23 And so in January, when Sandoz, when RareGen first learned of  
24 the issue with the cartridge restrictions, they immediately  
25 spring into action. They immediately start to try to figure

1 out what is going on here. But before 2019, there were no  
2 cartridge restrictions on the specialty pharmacies. And  
3 that's critical.

4 We cite to the testimony of each of the Sandoz and  
5 RareGen's employees that confirm this point. That's on page  
6 39 of our papers. And I want to show the Court just the  
7 initial pages of each of these agreements where there's  
8 finally the restriction. Because, again, April of 2019 is  
9 when that restriction comes into place.

10 Now, we can look also at the CVS, which is Exhibit 723,  
11 the May 2019 agreement.

12 Now, defendants, they -- the idea that a generic  
13 drugmaker would need to go out and develop and manufacture its  
14 own device, that's just wrong as a matter of fact and it's  
15 wrong as a matter of law. And Your Honor hit on a very  
16 critical point. It requires the Court to find that Sandoz  
17 would have or should have assumed that UTC was going to breach  
18 that patent settlement. And I want to take a look at that  
19 patent settlement because it's critical to this case.

20 So we have the settlement in September of 2015. It's  
21 Exhibit 1006, and it's clear, UTC was not to take any action,  
22 directly or indirectly, to prevent, delay, limit or otherwise  
23 restrict the launch.

24 Now, they keep pointing to a clause about the delivery  
25 devices, but that related to UTC-developed delivery devices.

1 There was no way for Sandoz and RareGen to know that UTC and  
2 Smith would get together and would sign agreements that  
3 effectively blocked the generic from entering the market by  
4 having these cartridge restrictions.

5 Now, the bottom line is that without UTC's blocking  
6 conduct, without the restrictions on the cartridges that  
7 weren't in place until April or May of 2019, Sandoz and  
8 RareGen would have brought a cheaper, lower cost generic to  
9 the market to serve subcutaneous patients. And as Mr. Glass  
10 said, it's important for us to be able to come to market and  
11 bring a product to reduce costs because that is what our  
12 companies are all about.

13 Now, Sandoz and RareGen did launch the IV. They chose  
14 in March of this year to launch in the IV space. And the  
15 reason they did that is because it's the right decision. It's  
16 the right decision morally. It's the right decision  
17 ethically. It's the right decision as a matter of law. And  
18 I'm sure that had Sandoz and RareGen decided not to launch in  
19 the IV space, UTC would have been thrilled because it would  
20 have continued. It would have allowed them to main their  
21 monopoly not just over the subcutaneous market through their  
22 blocking of the cartridges, but also over the IV space.

23 And, again, that, Your Honor, is just another  
24 diversion. It's another effort to try to avoid and misdirect  
25 the Court from the coercive and bad conduct of the defendants.

1           Your Honor, I'd like to provide the rest of my time to  
2 my co-counsel, Mr. Glass. Thank you.

3           MR. GLASS: Hello again, Your Honor.

4           THE COURT: How are you?

5           MR. GLASS: So with the last few minutes I would like  
6 to reflect upon what is not in dispute. What is not in  
7 dispute is as of today, there is no competitor to Remodulin®  
8 subcutaneous. As of today, the competition that RareGen and  
9 Sandoz bring to IV is severely impaired by the blocking of the  
10 subcutaneous route. As of today, UTC is making an incredible  
11 profit.

12           And I heard Smith's counsel say that they're innocent  
13 in all of this, but as we all know, they are a co-conspirator.  
14 They've engaged in overt acts. They are on the hook.  
15 Whatever contractual provisions they have between themselves  
16 are invalid and unenforceable. And they certainly can't be an  
17 excuse for engaging in any competitive conduct.

18           As of today, the defendants are blocking competition to  
19 the detriment of not only RareGen and Sandoz, but patients,  
20 prescribers, and payers.

21           They should not be allowed to benefit from that  
22 conduct. That's why the antitrust laws are here: To preserve  
23 competition. The only argument I really heard from defendants  
24 is that you should conflate pumps and cartridges. Because  
25 there was an end of life pump notice in 2015, we should assume

1 that everyone in the market knew the cartridges were going to  
2 be unavailable. But that's not consistent with the facts. As  
3 Mr. Kent noted, that end-of-life notice says in the end  
4 cartridges weren't end of life. And in fact, the cartridge  
5 end-of-life notice didn't come until this year.

6 Second, defendants are arguing that somehow their  
7 secret agreement to monopolize and extend the patent to block  
8 competition is something that we should have fixed. How can  
9 that be the standard in an antitrust case where the -- the  
10 plaintiffs not only need to somehow, without discovery, figure  
11 out what was going on, but then remedy it? We saw the slides  
12 about the alternative options. One option was new pumps. Two  
13 years. That's what the slide said. Two years. None of those  
14 are approved to be used in the United States. None can be  
15 approved for a long period of time.

16 We heard that all they want to do is serve Remodulin®  
17 patients. But Your Honor, the Remodulin® patients are  
18 everyone. So every patient we take, they don't need to serve.

19 As we heard from the president of the UTC, as well as  
20 many other witnesses, there is enough resin to make cartridges  
21 for ten years. There is no limit on cartridges except the  
22 limit that they've imposed on the specialty pharmacies to  
23 dispense them. This is not about them serving patients.

24 Finally, there's this notion that cartridges wouldn't  
25 exist but for the secret agreement. First, that's

1 self-serving testimony that doesn't match with the evidence.  
2 And Your Honor has plenty of evidence to review to see that  
3 that's just not true.

4           Smiths may have wanted to discontinue the pumps, but  
5 the cartridges are a different story. They didn't discontinue  
6 them. And Your Honor, as we engaged, if they had a problem  
7 with the profitability of the cartridges, the simple solution  
8 is to raise the price. In fact, had Smiths put the cartridges  
9 up for auction and said, look, UTC, bid against RareGen and  
10 Sandoz, they would have maximized the value of these  
11 cartridges. But instead, in a secret agreement, they sold  
12 them for pennies on the dollar. That's not our fault.

13           As we've said earlier today, if they're up for auction  
14 today, we would outbid UTC. That's how important these  
15 cartridges are to us.

16           So I don't want the distractions of all the timelines  
17 and all of the quotes to miss that today patients are losing  
18 out. And in fact, the patient assistance program shows  
19 exactly how they're losing out. It's not just that specialty  
20 pharmacies pay more. It's not just that insurers pay more.  
21 It's not just that Medicare and Medicaid pay more. All those  
22 should matter. It's that patients pay more.

23           Your Honor, this is a very important case. There are  
24 not a lot of people who take these, but those who do, it costs  
25 an incredible amount of money.

1 THE COURT: Okay.

2 MR. GLASS: Thank you, Your Honor.

3 THE COURT: Thank you.

4 Counsel.

5 MR. PITT: If Your Honor would permit me just a quick  
6 moment to respond to some of those points.

7 THE COURT: Sure.

8 MR. PITT: That would be wonderful. Thank you. I'll  
9 be very brief, Your Honor.

10 First, I wanted to point out that Mr. Kent pointed to  
11 an email from August 10th, 2017, in which Accredo said all you  
12 need to do is just give us the vials. I wanted to point out  
13 that there is another part of that timeline which is -- this  
14 is in our papers, but Sandoz had gotten a report from McKinzie  
15 that said due to the pump issues, there's a substantial chance  
16 of a delayed launch.

17 Sandoz then, in December of 2017, shut down its launch.  
18 They suspended it for those reasons. So the idea that that  
19 one Accredo email somehow gave them all of the certainty they  
20 needed in order to do a complex and very expensive launch like  
21 this doesn't really match with the evidence.

22 The end-of-life notice point, the end-of-life notice  
23 did pertain to cartridges. It -- what it states is that there  
24 will be enough cartridges to serve the then extent pumps.  
25 That is another three years.

1           The contemporaneous documents, which we've cited in our  
2 papers, demonstrate that had there been no restriction on the  
3 use of those cartridges, those cartridges only would have  
4 lasted until February 2019. That is a month before Sandoz and  
5 RareGen decided to launch. It was only through the Remodulin®  
6 only restrictions that they were projected to last until 2022  
7 at the outset.

8           The point about the supposedly coercive and extreme  
9 tactics taken with the specialty pharmacies, Your Honor, I  
10 would only say that their quotes are extremely selective.  
11 There is -- it is completely undisputed that every order for  
12 cartridges placed by a specialty pharmacy was fulfilled.  
13 Every single one. There was no denial of any order of  
14 cartridges. The witnesses testified that there were no  
15 threats. And, in fact, the witness who negotiated with the  
16 specialty pharmacies, not for the contract between Smiths and  
17 the specialty pharmacies, which were not never even executed,  
18 which they're talking about, but the United Therapeutics'  
19 contracts with the specialty pharmacies, he testified that  
20 there were absolutely no problems. They opted not to depose  
21 anyone from the specialty pharmacy. And I think it's fair to  
22 ask why that is.

23           Just a couple of other points. The -- what they say  
24 they want to do, they want to ask you to look at the aspects  
25 of the arrangement between Smiths and United Therapeutics that



1 they don't like and to condemn those without looking at the  
2 overall arrangement that existed and that the contemporaneous  
3 evidence shows always existed between those two parties. The  
4 law doesn't permit that kind of disaggregation of an economic  
5 relationship when analyzing the economic or competitive  
6 effects of it. And the evidence doesn't support that.

7           The settlement clause that says there is no entitlement  
8 to a delivery mechanism does reference other pumps made by  
9 third parties and delivery mechanisms made by third parties.  
10 And the -- I guess those are the primary points I wanted to  
11 address. Thank you, Your Honor.

12           THE COURT: Counsel, thank you very much.

13           I will permit a five-page closing, if you will. I was  
14 going to say 14 days, but that's a horrible end date. So  
15 seven. This way at least you can have a week and hopefully  
16 not focus on this case.

17           MR. BENNETT: Seven days. The 17th.

18           THE COURT: Let's see. Ten?

19           MR. GLASS: Your Honor, I mean, it's a long time for  
20 these cartridges to be unavailable.

21           THE COURT: Okay. You want three?

22           MR. GLASS: I don't speak for Sandoz, but we'll be  
23 prepared to submit as quickly as Your Honor can take it.

24           THE COURT: Seven?

25           MR. BENNETT: Seven is fine with us.

1 THE COURT: Seven. Okay. Anything further?

2 MR. GLASS: Thank you, Your Honor.

3 THE COURT: Counsel, thank you very much. Wonderful  
4 job in papers and verbally today. Enjoy the holidays as best  
5 you can. Thank you.

6 THE DEPUTY COURT CLERK: All rise.

7 (Court concludes at 12:33 p.m.)

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FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE.

- - - - -

I certify that the foregoing is a correct transcript from  
the record of proceedings in the above-entitled matter.

I

/S/ Megan McKay-Soule, RMR, CRR

December 11, 2019

Court Reporter

Date

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